**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| **IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION** | **MDL NO. 1871**<br>**07-md-1871** |
| **THIS DOCUMENT APPLIES TO: ALL THIRD-PARTY PAYOR ACTIONS** | |

# MEMORANDUM OPINION

**Rufe, J.** **October 25, 2024**

Plaintiffs, United Food and Commercial Workers Local 1776 and Participating Employers Health and Welfare Fund and J.B. Hunt Transport Services, Inc. (collectively, the "Plans"), filed suits against GlaxoSmithKline LLC ("GSK") alleging violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO") and various state consumer protection laws in connection with the marketing of the diabetes drug Avandia.[1] These actions were incorporated into the *In re Avandia Marketing, Sales Practices and Products Liability* Multi-District Litigation ("MDL").[2] The Plans seek to offer Meredith Rosenthal, Ph.D. as an economic expert on pharmaceutical demand and the effect of Avandia promotions on sales. The Plans also seek to offer Thomas McGuire, Ph.D. as a damages expert. Before the Court are GSK's motions to exclude the opinions and proposed testimony of Drs. Rosenthal and McGuire. The Court has reviewed Dr. Rosenthal and Dr. McGuire's expert reports, the rebuttal reports, and the parties' briefs, and heard evidence and argument at a *Daubert* hearing.

[1] There were originally four relevant third-party payor actions brought by: (1) Allied Services Division Welfare Fund ("Allied") (No. 09-730); (2) United Benefit Fund ("UBF") (No. 10-5419); (3) UFCW Local 1776 and Participating Employers Health and Welfare Fund ("UFCW") (No. 10-2475); and (4) J.B. Hunt Transport Services, Inc. ("J.B. Hunt") (No. 11-4013). The claims asserted by Allied and UBF have been voluntarily dismissed with prejudice. *See* Order, Nov. 10, 2016 [Doc. No. 5033]; Order, Nov. 22, 2016 [Doc. No. 5041]. Therefore, the Court will consider GSK's motions with respect to the actions brought by UCFW and J.B. Hunt.

[2] *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 07-md-1871 (E.D. Pa.).

## I. BACKGROUND

GSK produces, markets, and distributes oral medications to treat Type II diabetes mellitus under the brand names Avandia, Avandamet, and Avandaryl (collectively "Avandia").[3] The Plans are employee welfare benefit plans as defined by the Employee Retirement Income Security Act. The Plans provide medical coverage, including prescription drug coverage, to their members and their members' dependents. Along with other similarly situated third-party payors ("TPPs"), the Plans have paid for Avandia since the Food and Drug Administration ("FDA") approved it for sale in 1999.

TPPs generally have Pharmacy Benefit Managers ("PBMs") prepare a formulary, which is a list of drugs approved for coverage when prescribed to the TPPs' beneficiaries. In preparing the formulary, a PBM examines research regarding a drug's safety, efficacy, and benefits as compared to other forms of treatment, and also assesses cost-effectiveness. If one drug has some advantage over competing drugs, it can be given a priority status on the formulary, which means that a patient will pay a lower co-payment when his or her doctor prescribes that drug. Because PBMs rely on existing research, when a company acts to conceal material information about a drug's benefits, a PBM will not have the information it needs to make an informed decision.

The Plans in this case opted to include Avandia on their formularies, sometimes at a higher preference level than competing drugs, and covered Avandia prescriptions at the favorable formulary rate. The Plans assert that they relied in part on GSK's representations that Avandia was capable of both controlling a patient's blood sugar levels and reducing cardiovascular risk better than other available medications, such as metformin and sulfonylurea.

[3] As the Court has written at length on this matter, the background section is similar to the background section of a previous opinion for this case. *See In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 07-md-1871, 2017 WL 11619528, at *1–2 (E.D. Pa. Dec. 7, 2017). However, facts dispositive to resolving these motions have been added for clarity.

The Plans allege that, from 1999 to 2007, GSK engaged in deceptive marketing practices by failing to disclose information contradicting the purported cardiovascular benefits of Avandia as compared to other available medications. The Plans further allege that, had they been given this information prior to 2007, they would not have included Avandia on their formularies and would not have paid a higher premium for Avandia prescriptions over other diabetes drugs.

**A. History of Avandia Studies and FDA Labeling**[4]

On May 25, 1999, the FDA approved Avandia for sale. GSK continued to test Avandia's safety after its approval, with varied results. For example, GSK conducted a large, long-term, prospective, randomized, and controlled clinical trial designed to evaluate Avandia's cardiovascular outcomes, which it named the RECORD trial. This trial compared patients taking Avandia plus metformin or a sulfonylurea to those taking metformin plus sulfonylurea. The primary endpoints measured in the RECORD trial were cardiovascular deaths and hospitalizations, and the interim data did not show that Avandia lowered cardiovascular events more than comparators.[5]

GSK also conducted a meta-analysis of Avandia's cardiovascular risk using data collected from 37 clinical trials completed by September 2004.[6] In September 2005, GSK completed that meta-analysis ("ICT-37"), which found a hazard ratio point estimate of 1.29—suggesting that Avandia users were 1.29 times *more* likely to have an ischemic event than users of placebo or other anti-diabetic drugs—but the findings did not reach statistical significance at a 95% confidence interval.[7]

[4] The Court includes only those facts dispositive to the motions to exclude Drs. Rosenthal and McGuire.

[5] GSK's Resp. Opp'n Pls.' Affirmative Statement of Facts ¶ 230 [Doc. No. 5564] (filed under seal).

[6] Hr'g Tr. Feb. 1, 2024, at 88 [Doc. No. 5568].

[7] *Id.* at 103.

The following year, GSK expanded its meta-analysis to include 42 clinical trials ("ICT-42"). ICT-42 demonstrated a statistically significant association between Avandia and ischemic events, suggesting a 31% increase in the risk of such events. On May 21, 2007, Dr. Steven Nissen, an independent researcher, published an article (the "Nissen Study") on his own meta-analysis of past Avandia trials in the *New England Journal of Medicine*. The Nissen Study concluded that, when compared to a placebo or other antidiabetic regimens, Avandia was "associated with a significant increase in the risk of myocardial infarction and with an increase in the risk of death from cardiovascular causes that had borderline significance."[8]

On July 30, 2007, the FDA convened an advisory committee to evaluate the data on Avandia's cardiovascular safety and to recommend potential changes to its labeling. On November 14, 2007, the FDA directed GSK to add information to the Avandia label in a boxed warning, stating in part that "[a] meta-analysis of 42 clinical studies . . . , most of which compared AVANDIA to placebo, showed AVANDIA to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction."[9] After this warning was added to Avandia's label, sales of the drug declined.

In 2010, the FDA directed GSK to commission an independent re-adjudication of the RECORD trial. In the interim, the FDA imposed a revised label stating that Avandia would be available on a restricted basis because of a "potential increased risk of myocardial infarction."[10] In 2013, after the TPP lawsuits were filed, the FDA advisory committee examined the re-adjudicated results of the RECORD trial, which confirmed the initial RECORD results. In a

[8] *In re Avandia*, 2017 WL 11619528, at *5; Steve E. Nissen & Kathy Wolski, *Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes*, 356 N. Eng. J. Med., no. 24, June 2007, at 2457.

[9] *Id.* at *7.

[10] *Id.*

decisional memorandum dated November 19, 2013, the FDA wrote that "the data continue to support no statistically significant difference between rosiglitazone [Avandia] and metformin/sulfonylurea for the risk of death or major adverse cardiovascular outcomes, other than the known class effect of heart failure."[11] Rather, the FDA stated, "the RECORD trial, and its re-adjudication, provide considerable reassurance regarding the cardiovascular safety of rosiglitazone."[12] On May 7, 2014, the FDA approved an updated label that removed the cardiovascular risk and restricted access information from the boxed warning. By this time, however, Avandia sales had dwindled, and the drug was no longer widely prescribed.

**B. Procedural History**

On December 7, 2017, this Court granted summary judgment in favor of GSK on the Plans' RICO claims, reasoning in part that the Plans were belated in pursuing arguments that GSK improperly marketed Avandia's benefits—as distinct from GSK's alleged fraudulent concealment of Avandia's *increased* cardiovascular risks when compared to alternatives.[13] The Third Circuit reversed, holding that "'better cardiovascular outcomes' were a crucial part of GSK's alleged fraudulent marketing," and it remanded for further proceedings on the Plans' theory that GSK promised "superior treatment and better cardiovascular outcomes compared with the older diabetes drugs . . . ."[14] The Third Circuit further explained:

[11] *Id.*

[12] *Id.*

[13] *Id.* at *2, *8.

[14] *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 945 F.3d 749, 762 (3d Cir. 2019) [hereinafter *Avandia II*].

> While a portion of the Plans' claims center on the assertion that GSK should have disclosed on its label the true nature of the increased cardiovascular *risk* that was presented by Avandia as compared to cheaper alternatives, the increased risk is only relevant to the Plans' claims insofar as the Plans make the following argument: GSK failed to warn of Avandia's true cardiovascular *risk*, and thus, GSK was continuing—by omission—to promote Avandia as capable of *lowering* patients' cardiovascular risk, and GSK thereby continued to induce the Plans to cover the cost of Avandia based on this perceived "benefit" of lowering cardiovascular risk. . . . In short, the Plans have never argued that GSK promoted Avandia as capable of actually *improving* patients' cardiovascular health, but rather as capable of *lowering cardiovascular risk* when compared to cheaper alternatives, which indeed is a "benefit."[15]

After the conclusion of discovery following remand, the Plans moved for class certification pursuant to Federal Rule of Civil Procedure 23(b)(3);[16] GSK filed motions to exclude six of the Plans' experts;[17] the Plans moved to exclude two of GSK's experts;[18] and GSK moved for summary judgment.[19] In accordance with established precedent in this Circuit, this Court entered an Order requiring that the parties identify experts critical to proving the requirements for class certification under Rule 23.[20] Upon consideration of the parties' joint letter in response to the Order,[21] the Court held a *Daubert* hearing to hear testimony and oral argument on GSK's motions to exclude Drs. Rosenthal and McGuire. The Court now addresses those two motions.

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[15] *Id.* (citation omitted).

[16] Pls.' Mot. Class Cert. [Doc. No. 5501].

[17] Def.'s Mots. Exclude Russell, Kesselheim, McGuire, Farooki, Rosenthal, & Perry [Doc. Nos. 5524–29].

[18] Pls.' Mot. Exclude Jena & Hughes [Doc. No. 5522].

[19] Def.'s Mot. Summ. J. [Doc. No. 5532].

[20] Order, Nov. 29, 2023 [Doc. No. 5562]. *See In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187–88 (3d Cir. 2015) (holding that the "rigorous analysis" required for class certification necessarily "applies to expert testimony critical to proving class certification requirements") (quoting *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013)); *see also Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350–51 (2011); *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 323 (3d Cir. 2008).

[21] Doc. No. 5565.

## II. LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence provides that:

> [a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.[22]

The focus of the Court's inquiry must be on the expert's methods, not the expert's conclusions. The Third Circuit has interpreted Rule 702 as setting forth three requirements: (1) the expert must be qualified; (2) the expert must testify about matters requiring scientific, technical, or specialized knowledge; and (3) the expert's testimony must assist the trier of fact.[23] "The proponent of the expert testimony bears the burden to show by a preponderance of the evidence that their expert's opinion is reliable."[24] District courts have "broad discretion in determining the admissibility of evidence, and 'considerable leeway' in determining the reliability of particular expert testimony . . . ."[25]

"[A]n expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable."[26] An expert's opinion is reliable if it is "based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation

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[22] Fed. R. Evid. 702.

[23] *Pineda v. Ford Motor Co*., 520 F.3d 237, 244 (3d Cir. 2008); *accord In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741–43 (3d Cir. 1994).

[24] *Whyte v. Stanley Black & Decker, Inc.*, 514 F. Supp. 3d 684, 691 (W.D. Pa. 2021) (citing *Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000)).

[25] *Walker v. Gordon*, 46 F. App'x 691, 694 (3d Cir. 2002) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152–53 (1999)).

[26] *Paoli*, 35 F.3d at 742.

. . . .'"[27] The experts must have good grounds for their opinions, but not necessarily the best grounds or unflawed methods.[28] Courts must consider:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.[29]

A court must also determine whether the expert's testimony will assist the trier of fact—*i.e.*, it must evaluate "the 'fit' of the expert's testimony as it relates to the case at hand . . . ."[30] The fit requirement "goes primarily to relevance."[31]

## III. DISCUSSION

### A. Dr. Meredith Rosenthal

The Plans seek to offer Meredith Rosenthal, Ph.D. as an economic expert on pharmaceutical demand and the effect of Avandia promotions on sales. In her expert reports, Dr. Rosenthal renders two key opinions. First, she asserts "that the alleged mischaracterization of the benefits and risks associated with Avandia franchise products was a substantial contributing factor to TPP class members' purchases of Avandia franchise products."[32] Second, she determines that 41% of Avandia sales from January 2005 to August 2007 were caused by GSK's fraudulent promotion—in other words, that in a but-for world where GSK had not fraudulently marketed Avandia, there would have been 41% fewer sales as compared to actual sales during

[27] *Id.* (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993)).

[28] *See Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 784 (3d Cir.1996); *Paoli*, 35 F.3d at 744–45.

[29] *Pineda*, 520 F.3d at 247–48 (citing *Paoli*, 35 F.3d at 742 n.8).

[30] *Macaluso v. Apple, Inc.*, No. 21-1361, 2023 WL 4685965, at *4 (E.D. Pa. July 21, 2023).

[31] *Daubert*, 509 U.S. at 591.

[32] Hileman Decl., Ex. 1, Rosenthal Rep., at 1 [Doc. No. 5530-1].

that period.[33] Dr. Rosenthal's opinions are based on an econometric model she built using a multiple regression analysis that, she maintains, identifies a statistically significant relationship between GSK's marketing and Avandia sales.

GSK does not challenge Dr. Rosenthal's expertise in health economics, but does challenge her qualifications to make assumptions about whether GSK reasonably could have completed the ICT-37 meta-analysis by January 2005, and whether an earlier release of ICT-37 would have been publicized in a substantially similar way as the Nissen Study. GSK also argues that Dr. Rosenthal employs flawed methodology which is not supported by the relevant community of economists or published research in the field. Specifically, GSK contends that Dr. Rosenthal's model is results-oriented because the variable she uses to capture GSK's marketing efforts, by design, is such that any input variable would find a correlation with Avandia sales. Finally, GSK asserts that Dr. Rosenthal's opinion does not fit the issues in this case and would not assist the factfinder because it is insufficiently tailored to the Plans' theory of liability—*i.e.*, that GSK fraudulently marketed Avandia's cardiovascular benefits, as opposed to the now-foreclosed theory that GSK misled the public about Avandia's *greater* cardiovascular risks when compared to alternatives.

1. Qualifications to Make Certain Assumptions

Dr. Meredith Rosenthal is a Professor of Health Economics and Policy at the Harvard T.H. Chan School of Public Health.[34] She has an A.B. in International Relations from Brown

[33] Hileman Decl., Ex. 2, Rosenthal Rebuttal Rep., at 3, 18 tbl.1 [Doc. No. 5535-1] (filed under seal). Dr. Rosenthal reached the 41% figure in her rebuttal report, after "correcting a programming error" that had been identified by GSK's expert, Dr. Anupam Jena. *Id.* at 3, 17. Dr. Rosenthal's rebuttal report contends "that the correction in the computation . . . has no meaningful effect on the model results." *Id.* at 19.

[34] Hileman Decl., Ex. 1, Rosenthal Rep., at 2 [Doc. No. 5530-1].

University and a Ph.D. in Health Policy (Economics Track) from Harvard University.[35] She has worked as an expert in health economics since 1996 and has submitted written reports and oral testimony in many cases involving the healthcare market and pharmaceutical industry.[36] GSK does not challenge Dr. Rosenthal's expertise in health economics.

However, with regard to her opinion in these actions, GSK challenges Dr. Rosenthal's qualifications to make assumptions about two discrete issues. First, Dr. Rosenthal assumes in her report that GSK could and should have disclosed the ICT-37 results—which she states were indicative of Avandia's cardiovascular risks and lack of benefits—no later than January 1, 2005.[37] GSK asserts that Dr. Rosenthal is not a clinical expert, has only ever published one meta-analysis, and therefore is unqualified to opine about whether GSK reasonably could have completed the ICT-37 meta-analysis by that earlier date.[38] Second, Dr. Rosenthal assumes that the impact of earlier disclosure of ICT-37 results would be "substantially similar to what actually occurred in May 2007 when the [Nissen Study] was published and the FDA required additional product warnings on Avandia franchise products."[39] GSK argues that Dr. Rosenthal has not been offered as an expert in media, and therefore she is not qualified to opine on whether an earlier release of ICT-37 would have been publicized to the same degree as the Nissen Study.[40]

"As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis

[35] *Id.* at 4.

[36] *Id.* at 2–3; *id.*, Attach. A.

[37] *Id.* at 1, 40.

[38] GSK's Mem. Supp. Mot. Exclude Rosenthal at 6 n.4 [Doc. No. 5528-1].

[39] Hileman Decl., Ex. 1, Rosenthal Rep., at 40 [Doc. No. 5530-1].

[40] GSK's Reply Supp. Mot. Exclude Rosenthal at 9 [Doc. No. 5558].

for the opinion in cross-examination."[41] Exclusion is required only where "the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury . . . ."[42]

With respect to whether ICT-37 could have been completed earlier, GSK's objection is directed more toward the factual underpinnings of Dr. Rosenthal's assumption (based on disagreements over the record) than her qualifications to make that assumption. Notably, Dr. Rosenthal does not purport to have the expertise to arrive at that assumption independently—rather, she relies on the conclusion reached by one of the Plans' clinical experts, Dr. Thomas Perry.[43] GSK challenges Dr. Rosenthal's reliance on Dr. Perry's report, including by questioning whether Dr. Perry reached any conclusions specifically about how quickly the ICT-37 meta-analysis could have been conducted.[44] Dr. Perry opined in his report that "GSK had knowledge of adverse ischemic cardiovascular effects of Avandia as early as the fourth quarter of 1997," and that "GSK should have disclosed Avandia's adverse cardiovascular results to the healthcare community . . . certainly no later than January 1, 2005."[45] At bottom, the dispute between the parties centers "on competing versions of the facts," and Dr. Rosenthal's assumption does not rise to the level of being so fundamentally unsupported by the record that exclusion is required.[46]

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[41] *Sterling v. Redevelopment Auth. of City of Phila.*, 836 F. Supp. 2d 251, 271–72 (E.D. Pa. 2011) (quoting *Child.'s Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 865 (8th Cir. 2004)); *see also JMJ Enters., Inc. v. Via Veneto Italian Ice, Inc.*, No. 97-652, 1998 WL 175888, at *6 (E.D. Pa. Apr. 15, 1998) ("Questions as to the sufficiency of an expert's factual basis are generally left to the jury.").

[42] *Sterling*, 836 F. Supp. 2d at 572 (quoting *Child.'s Broad. Corp.*, 357 F.3d at 865).

[43] Hr'g Tr. Feb. 1, 2024, at 50, 90 [Doc. No. 5568]; *see also* Hileman Decl., Ex. 3, Rosenthal Dep. Tr. June 8, 2023, at 97 [Doc. No. 5530-3].

[44] GSK's Mem. Supp. Mot. Exclude Rosenthal at 4–6 [Doc. No. 5528-1]; Hr'g Tr. Feb. 1, 2024, at 94–95 [Doc. No. 5568].

[45] Hileman Decl., Ex. 5, Perry Rep., at 414–15 [Doc. No. 5530-5].

[46] *In re Mushroom Direct Purchaser Antitrust Litig.*, No. 06-0620, 2015 WL 5767415, at *6 (E.D. Pa. July 29, 2015) (quoting Fed. R. Evid. 702 advisory committee's notes to 2000 amendments).

Likewise, Dr. Rosenthal's second assumption—that the impact of releasing the results of ICT-37 earlier would have been comparable to the publication of the Nissen Study—is not so divorced from the record that it warrants exclusion. GSK highlights differences between ICT-37 and the Nissen Study, such as the fact that the Nissen Study reported results that were statistically significant, whereas ICT-37 did not. Dr. Rosenthal testified at her deposition that "statistical significance is just a threshold," the ICT-37 findings "would have been statistically significant at a 90 percent confidence level," and "holding those two sets of results beside each other, the signal is effectively the same even though they're on either side of the threshold."[47] More important, Dr. Rosenthal clarified at her deposition that she is relying not on her own opinions, but rather on the opinions of the Plans' clinical experts "that the signal from ICT 37 was serious enough that prescribers would have been advised of it" and that "that information would have been clinically meaningful to prescribers."[48]

Along similar lines, GSK argues that the Nissen Study found that Avandia was more dangerous than other diabetes treatments, whereas ICT-37 did not reach such a conclusion.[49] The Plans respond that "GSK misreads Nissen," because the Nissen Study concluded that use of Avandia "as compared with placebo or with other antidiabetic regimens . . . was associated with a significant increase in the risk of myocardial infarction . . . ."[50] In other words, according to the Plans, Nissen and ICT-37 *both* compared Avandia to other diabetic treatments and placebo, and

[47] Hileman Decl., Ex. 3, Rosenthal Dep. Tr. June 8, 2023, at 29, 166 [Doc. No. 5530-3]; *see also* Hr'g Tr. Feb. 1, 2024, at 102–03, 115 [Doc. No. 5568] (stating that the results had a confidence interval of .99 to 1.69 and would have been statistically significant at a 90% confidence interval, even if not 95%). Notably, the Third Circuit observed on appeal that by GSK's own admission, ICT-37 and ICT-42 (the latter of which did lead to statistically significant findings) "indicated similar results and had clinically insignificant numerical differences." *Avandia II*, 945 F.3d at 760.

[48] Hileman Decl., Ex. 3, Rosenthal Dep. Tr. June 8, 2023, at 167 [Doc. No. 5530-3].

[49] GSK's Mem. Supp. Mot. Exclude Rosenthal at 6 [Doc. No. 5528-1].

[50] Pls.' Resp. Opp'n Mot. Exclude Rosenthal at 14 [Doc. No. 5542] (emphasis omitted).

both found an association with an increased risk of myocardial ischemic events.[51] The dispute therefore circles back to a disagreement over how important the difference in statistical significance between each study would have been to prescribers and the public.[52] Such factual disagreements over the best clinical interpretation of each study's results and how those results would have been received do not provide a basis for exclusion.[53]

2. Reliability

In order to reach her conclusions, Dr. Rosenthal uses multiple regression, which she describes as "a standard econometric technique."[54] As explained in her opening report, "[m]ultiple regression techniques allow the analyst to separately quantify the influence of multiple economic variables on an outcome."[55] Dr. Rosenthal specifically uses time-series regression, which "examines patterns over time for a single unit of analysis (here, the United States retail pharmaceutical market) to capture the underlying causal relationship of interest."[56] Dr. Rosenthal's regression model (the "Rosenthal Model") is designed to determine whether and to what extent there was a causal relationship between, on the one hand, GSK's marketing of Avandia, and on the other hand, sales of Avandia, while controlling for other factors.[57]

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[51] *See id.*

[52] *See* Hr'g Tr. Feb. 1, 2024, at 115–16 [Doc. No. 5568].

[53] GSK separately raises that there is no basis to assume that an earlier release of ICT-37 would have resulted in a national media campaign of comparable reach as that which followed the Nissen Study's publication. GSK's Mem. Supp. Mot. Exclude Rosenthal at 6–7 [Doc. No. 5528-1]. During the hearing, Dr. Rosenthal conveyed her belief "that the information was important enough that it would have gotten picked up" by the media. Hr'g Tr. Feb. 1, 2024, at 112 [Doc. No. 5568]. As with GSK's other objections, this issue may provide a basis for cross-examination, but does not rise to level of requiring exclusion, particularly given Dr. Rosenthal's reliance on the Plans' other experts regarding the clinical significance of the findings and how they would be received by the public.

[54] Hileman Decl., Ex. 1, Rosenthal Rep., at 34 [Doc. No. 5530-1].

[55] *Id.*

[56] *Id.* at 35.

[57] *See id.* at 36–37 (expressing time-series linear regression model as a multivariable formula).

*a. Stock of Promotion Variable*

The key "explanatory variable" in the Rosenthal Model is the one intended to capture GSK's marketing of Avandia. Her report refers to this variable as the "stock of promotion" for Avandia (the "own-promotion stock").[58] The own-promotion stock is constructed using data reflecting GSK's actual expenditures in connection with its promotion of Avandia, including dollars spent over time on detailing (*i.e.*, visits or phone calls by sales representatives to physicians), samples, and journal advertising.[59] In constructing the own-promotion stock variable, Dr. Rosenthal adopts an approach called the "perpetual inventory model," which is based on the economic principle that "the month-to-month *flow* of real promotional expenditures accumulates into a *stock* of promotional inventory that depreciates over time."[60]

The perpetual inventory model is premised on the notion that the effects of advertising accumulate over time because physicians (or patients) who become more familiar with a particular drug tend to prescribe or request it more often.[61] A depreciation rate is intended to account for some discounting, or forgetting, that occurs with respect to the long-lasting effects of the promotion over time. Dr. Rosenthal agreed at the hearing that the depreciation rate "tells you how long a unit of promotion continues to affect sales," and "[t]he higher the depreciation rate, the sooner a unit of promotion leaves the stock."[62] Dr. Rosenthal also testified that the

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[58] *Id.* at 35.

[59] *Id.* at 19, 30–31 (describing promotional spending data obtained from IQVIA, an independent data provider).

[60] *Id.* at 35 (citing Ernst R. Berndt et al., *Information, Marketing, and Pricing in the U.S. Antiulcer Drug Market*, 85 Am. Econ. Rev., no. 2, May 1995, at 100; Ernst R. Berndt et al., *The Roles of Marketing, Product Quality, and Price Competition in the Growth and Composition of the U.S. Antiulcer Drug Industry*, *in* The Economics of New Goods 277 (Timothy F. Bresnahan & Robert J. Gordon eds., 1996); John A. Rizzo, *Advertising and Competition in the Ethical Pharmaceutical Industry: The Case of Antihypertensive Drugs*, 42 J.L. & Econ. 89 (1999); Füsun F. Gönül et al., *Promotion of Prescription Drugs and Its Impact on Physicians' Choice Behavior*, 65 J. Mktg., no. 3, July 2001, at 79).

[61] Hileman Decl., Ex. 1, Rosenthal Rep., at 22 [Doc. No. 5530-1]; Rizzo, *supra* n.60, at 96.

[62] Hr'g Tr. Feb. 1, 2024, at 63 [Doc. No. 5568].

depreciation rate of the own-promotion stock variable "is an output of the analysis," meaning the model calculates an optimal depreciation rate that "best predict[s] sales . . . ."[63] The Rosenthal Model calculates two depreciation rates—1.3% before May 2007, and 45.8% after May 2007—on the theory that the "negative informational shock" of the Nissen Study "would be expected to cause a deterioration of the stock of 'good will' for an experience good like a prescription drug."[64] Dr. Rosenthal cites economic studies for the proposition that such "structural breaks" may be introduced "when market conditions change at a clearly demarcated point in time."[65]

*b. Calculation of Depreciation Rates and Falsification Analysis*

GSK argues that the steps Dr. Rosenthal took to construct the own-promotion stock variable are results-oriented and entirely undermine the reliability of her model. GSK asserts that Dr. Rosenthal "did not select these depreciation rates based on literature or theory," but rather "simply used a trial-and-error approach until she found rates 'that . . . yield the best fit,'" such that the model identifies a close relationship between GSK's promotion and Avandia sales "regardless of whether those rates made any sense as a matter of logic."[66] GSK also contends that, in particular, Dr. Rosenthal's use of two depreciation rates allows her model to "perfectly mirror the pre- and post-May 2007 trends in Avandia sales" in a results-oriented manner, and represents a departure from the literature and her prior methodologies in other cases.[67]

As an illustration, GSK's responsive expert, Dr. Jena, conducted a falsification analysis wherein he replaced the input variable in Dr. Rosenthal's model with datasets having no

[63] *Id.* at 63, 70.

[64] Hileman Decl., Ex. 2, Rosenthal Rebuttal Rep., at 12, 17 [Doc. No. 5535-1].

[65] *Id.* at 12; GSK's Reply Supp. Mot. Exclude Rosenthal at 3 [Doc. No. 5558].

[66] GSK's Mem. Supp. Mot. Exclude Rosenthal at 8 [Doc. No. 5528-1] (quoting Hileman Decl., Ex. 2, Rosenthal Rebuttal Rep., Attach. C ¶ 13 [Doc. No. 5530-1]).

[67] *Id.* at 9.

connection to Avandia and bearing no resemblance to Avandia promotional expenditures—specifically, monthly beef production, Colorado River flows, U.S. carbon emissions, and Hershey's expenditures.[68] In each case, Dr. Jena employed Dr. Rosenthal's methodology (including her use of two depreciation rates) and found a positive and statistically significant relationship with Avandia sales.[69] Dr. Rosenthal agreed during the hearing that, "in theory," one "would not expect to see any relationship between the data from these random variables and Avandia sales . . . ."[70] She also confirmed that she has not identified *any* datasets that would fail to result in a statistically significant relationship with Avandia sales using her parameters.[71]

*c. Daubert Factors*

An expert's conclusions must be "supported by good grounds for each step in the analysis," meaning "*any* step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible, . . . whether the step completely changes a reliable methodology or merely misapplies that methodology."[72] Use of the perpetual inventory model is well supported by the relevant community of economists. However, Dr. Rosenthal's methodology in this case—namely, her use of two depreciation rates and her reliance on a single model for sales of one drug—deviates from the literature in substantial and important ways.

As Dr. Rosenthal conceded at the hearing, her report does not cite a single study that implements a structural break permitting the use of two depreciation rates to optimize a

[68] Hileman Decl., Ex. 4, Jena Rep., Ex. 11 [Doc. No. 5535-2] (filed under seal). The Plans have moved to exclude Dr. Jena only on narrow grounds unrelated to his falsification analysis. *See* Pls.' Mem. Supp. Mot. Exclude Jena & Hughes [Doc. No. 5534-1] (filed under seal).

[69] Hileman Decl., Ex. 4, Jena Rep., at 72 [Doc. No. 5535-2] (filed under seal).

[70] Hr'g Tr. Feb. 1, 2024, at 82 [Doc. No. 5568].

[71] *Id.* at 85–86.

[72] *Paoli*, 35 F.3d at 742 (footnote and emphasis omitted).

predictive model's fit with the data.[73] Dr. Rosenthal further testified that she has not previously used any such methodology herself, "because [she has] not looked at a similar situation."[74] In her rebuttal report, Dr. Rosenthal contends that "[m]any economic studies introduce structural breaks analogous to this one . . . ."[75] However, the studies she cites do not purport to identify a causal relationship between marketing and sales or apply a structural break when constructing a cumulative promotional stock variable in a time-series regression.[76]

The studies Dr. Rosenthal cites that *do* involve pharmaceutical marketing are distinguishable from her model in this case. None uses two different depreciation rates to better fit a promotional stock variable to the data. They also apply strict structural parameters to analyze the *relative* effects of promotion across several drugs in a specified market, as opposed to making causal claims constrained within a single model regarding a single drug.[77] During the hearing, Dr. Rosenthal testified that her depreciation rates were calculated in the same manner as another study she cites, published by Berndt, Kyle, and Ling.[78] That study, however, assessed numerous brand name and generic pharmaceutical products (antiulcer and heartburn drugs)

[73] Hr'g Tr. Feb. 1, 2024, at 78 [Doc. No. 5568].

[74] *Id.*

[75] Hileman Decl., Ex. 2, Rosenthal Rebuttal Rep., at 12 [Doc. No. 5535-1].

[76] *Cf.* Jushan Bai, *Estimation of a Change Point in Multiple Regression Models*, 79 Rev. Econ. & Stat., no. 4, Nov. 1997, at 551 (analyzing relationship between changes in market interest rates and changes in discount rate); Bruce E. Hansen, *The New Econometrics of Structural Change: Dating Breaks in U.S. Labor Productivity*, 15 J. Econ. Perspectives, no. 4, Autumn 2001, at 117 (implementing structural breaks to analyze "slow-down" and "speedup" of U.S. labor productivity over decades).

[77] *See* Berndt et al. (1995), *supra* n.60 (measuring relative impact of promotion on market share among four antiulcer drugs with varying points of entry into the market); Berndt et al. (1996), *supra* n.60 (same); Rizzo, *supra* n.60 (using market-specific dataset that includes "a cross section and time series of most branded antihypertensive drugs in the United States").

[78] Hr'g Tr. Feb. 1, 2024, at 69 [Doc. No. 5568]; Ernst R. Berndt, Margaret Kyle, & Davina Ling, *The Long Shadow of Patent Expiration: Generic Entry and Rx-to-OTC Switches*, *in* Scanner Data and Price Indexes 229 (Robert C. Feenstra & Matthew D. Shapiro eds., 2003).

across broader U.S. market segments.[79] Dr. Rosenthal's own work in other contexts is distinguishable on similar grounds. In the *In re Neurontin Marketing and Sales Practices Litigation*, for example, Dr. Rosenthal conducted a regression analysis intended to capture the effect of fraudulent off-label marketing.[80] To do so, Dr. Rosenthal constructed *separate models* for distinct indications and specialties corresponding with *each category* of off-label promotion, while using only one depreciation rate for each type of promotion.[81]

Put simply, the 45.8% depreciation rate the Rosenthal Model calculated for post-May 2007 Avandia sales, the methodology by which Dr. Rosenthal calculated that rate in the context of this model, and Dr. Rosenthal's use of two depreciation rates in the first instance, are not supported by the relevant community of economists or published research in the field.[82] To the contrary, Dr. Rosenthal's efforts to identify the depreciation rates that "best fit" the data, in the context of a single model involving all marketing and all sales with respect to a single drug, are suggestive of a methodology that is results-oriented and which "invert[s] the scientific method."[83] Because these individual steps diverge from established methods in the community, and because the results-oriented nature of the model is further confirmed by Dr. Jena's

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[79] Berndt et al. (2003), *supra* n.78 (examining the impact of marketing across distinct brands and generics in anticipation of patent expiration).

[80] *See In re Neurontin Mktg. & Sales Pracs. Litig.*, No. 04-10739, 2011 WL 3852254 (D. Mass. Aug. 31, 2011).

[81] *Id.* at *32–33; Hileman Decl., Ex. 4, Jena Rep. Ex. 11, at 74 [Doc. No. 5535-2] (filed under seal). GSK also notes that in *In re Celexa and Lexapro Marketing and Sales Practices Litigation*, No. 09-md-2067 (D. Mass.), Dr. Rosenthal directed another expert, Dr. Christopher Baum, to implement a structural break, but kept the depreciation rate the same while changing only the promotion variable coefficient. When asked during her deposition why she chose to change the depreciation rate rather than coefficient in this case, Dr. Rosenthal responded that "[t]his is the model that fit the data best," Hileman Decl., Ex. 3, Rosenthal Dep. Tr. June 8, 2023, at 207 [Doc. No. 5530-3], and an "earlier model . . . that had the coefficient difference . . . didn't fit the data as well," *id.* at 208–09.

[82] *See* Hr'g Tr. Feb. 1, 2024, at 69–70 [Doc. No. 5568] ("I did not cite any source. I cited the facts of this case."); *id.* at 129 ("There was no paper that used that same rate.").

[83] *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *14 (E.D. Pa. Feb. 1, 2001); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 796 (3d Cir. 2017) (an expert's analysis must be "truly a methodology, rather than a mere conclusion-oriented selection process" (citation omitted)).

falsification analysis (which Dr. Rosenthal has failed to persuasively rebut),[84] the Rosenthal Model is fundamentally unreliable and does not withstand scrutiny under Rule 702.[85]

3. Fit

The Third Circuit has held that GSK's alleged failure to disclose an increased cardiovascular risk posed by use of Avandia is relevant to the Plans' theory of liability only insofar as the omission of Avandia's true risk profile enabled GSK to continue promoting Avandia as capable of lowering cardiovascular risk.[86]

GSK argues that the Rosenthal Model "answers the wrong question," because it treats the hypothetical earlier disclosure of ICT-37 as having the same impact that the Nissen Study did, and the Nissen Study found that Avandia was more dangerous for the heart than alternative treatments.[87] The central issues of fact in the case, GSK contends, are "whether and to what extent GSK misrepresented the cardiovascular benefits of Avandia, and whether and to what extent GSK omitted information that would have disclosed Avandia's lack of cardiovascular

[84] The Plans assert that Dr. Jena's falsification results go to the weight given to Dr. Rosenthal's analysis, not its admissibility. Pls.' Resp. Opp'n Mot. Exclude Rosenthal at 10 [Doc. No. 5542]. The Plans point to *In re Mushroom Direct Purchaser Antitrust Litigation*, where the court admitted expert testimony despite the opposing expert's falsification results, which identified false positives in the challenged expert's regression analysis. 2015 WL 5767415, at *14. But in *In re Mushroom*, the false positives were *still related* to the data in question, they were just in a geographic region outside the market analyzed in the challenged expert's analysis. Here, unlike in *In re Mushroom*, all parties agree that the time-series datasets used in Dr. Jena's falsification analysis are far afield of anything having to do with Avandia sales. As things stand, we have no way of knowing whether the significant relationship between GSK's promotion and Avandia sales identified by Dr. Rosenthal's model are any more accurate than the obviously false relationships it identifies between Avandia sales and monthly beef production, Colorado River flows, U.S. Carbon emissions, and Hershey's expenditures. *See In re Rail Freight Fuel Surcharge Litig.*, MDL No. 1869, 725 F.3d 244, 254 (D.C. Cir. 2013). Dr. Jena's falsification results demonstrate the fundamental unreliability of the model and support exclusion under *Daubert*.

[85] The Plans raise the separate point that GSK itself conducted regression analyses internally to evaluate its promotional efforts. Dr. Jena, GSK's expert, also agrees that regression models are regularly used by economists. The Plans have not put forth any evidence that GSK's internal regressions were structured with similar parameters as those used in Dr. Rosenthal's model, which deviates from those in the literature and other cases.

[86] *Avandia II*, 945 F.3d at 762.

[87] GSK's Mem. Supp. Mot. Exclude Rosenthal at 11 [Doc. No. 5528-1].

benefits."[88] GSK avers that Dr. Rosenthal's analysis is not tailored to those questions, specifically because it does not "isolate the impact of the affirmative cardioprotective messaging that is the conduct underlying plaintiffs' liability case," and thus will not assist the trier of fact and must be excluded.[89]

The Court disagrees. GSK's fit argument relies on their interpretation that the Nissen Study only found that Avandia was more dangerous for the heart than alternative treatments, a claim they argue that Plaintiffs are no longer pursuing. But the Plans urge that the Nissen study *also* found that Avandia was associated with increased risk compared to the placebo, and so is similar enough to ICT-37 to act as a sufficient natural experiment and to fit their remaining claim that GSK should have disclosed the ICT-37 results. The Court has already explained that such factual disagreements over the best clinical interpretation of each study's results and how those results would have been received do not provide a basis for exclusion.[90] And, the Third Circuit has held that GSK's alleged failure to disclose an increased cardiovascular risk posed by use of Avandia is indeed relevant to the Plans' theory of liability.[91] Because Dr. Rosenthal's analysis "bakes in, at least to an extent" plaintiff's theory of liability, the use of the impact of the Nissen study as a proxy for ICT-37 is acceptable for *Daubert* purposes.[92]

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[88] GSK's Mem. Supp. Mot. Exclude Rosenthal at 12-13 [Doc. No. 5528-1].

[89] GSK's Mem. Supp. Mot. Exclude Rosenthal at 13 [Doc. No. 5528-1].

[90] *Supra* Section III.A.1.

[91] *Avandia II*, 945 F.3d at 762.

[92] *In re Processed Egg Products Antitrust Litigation*, 81 F. Supp. 3d 412, 435 (E.D. Pa. 2015) (holding that regression analysis using proxy was not a fit issue at the *Daubert* stage). In support of its fit argument, GSK cites to *Hoefling v. U.S. Smokeless Tobacco Co.*, 576 F. Supp. 3d 262 (E.D. Pa. 2021), arguing that the Court must exclude Dr. Rosenthal's opinion because it fails to sufficiently "separate out the effect of cardioprotective message from the effect of disclosures that Avandia was more dangerous than alternative treatments." GSK's Mem. Supp. Mot. Exclude Rosenthal at 14 [Doc. No. 5528-1]. This case is unhelpful here, though, because it dealt with two separate defendants and the increased risk of tonsil cancer allegedly associated with both of their products. *Hoefling*, 576 F. Supp. 2d at 268. The court excluded the causation expert there because he failed to isolate the effects of one tobacco product from the other and failed to opine specifically whether the two tobacco products at issue caused tonsil cancer. *Id.* at 276. The fit concern here is distinguishable, where the theory of liability—as the Third Circuit

The Rosenthal Model is unreliable for the reasons discussed above, but its fit is not the issue. Because Dr. Rosenthal's methodology is results-oriented, unsupported by the literature, and unreliable, the Court will grant GSK's motion to exclude her opinions under Rule 702.

**B. Dr. Thomas McGuire**

As the Third Circuit has previously explained, there are two available theories of damages in this case: (a) the "quantity effect" theory, *i.e.*, "the difference between what Avandia coverage cost and the cost of coverage of cheaper, safer drugs"; and (b) the "excess price" theory, *i.e.*, "the overvaluation of Avandia caused by GSK's misrepresentations."[93] At this stage, the Plans are not pursuing the latter "excess price" theory based on alleged price inflation.[94]

The Plans seek to offer Dr. Thomas McGuire as their damages expert. Dr. McGuire contends that damages can be calculated on a class-wide basis and presents two alternative damages scenarios based on two different time periods: first, from January 2005 to August 14, 2007 ("Scenario 1"), and second, from May 1999 to August 14, 2007 ("Scenario 2").[95] Dr. McGuire also offers two methods for calculating damages in Scenario 1. First, he uses the 41% figure Dr. Rosenthal identified using her regression model, which Dr. McGuire calls the "Rosenthal Adjustment."[96] Second, in the alternative, he applies a "Step-Down Adjustment," by which he applies the percentage decline in sales after the 2007 publication of the Nissen Study backwards to January 2005, based on the assumption that the level of decline would have been

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confirmed—does not depend on separating out the impact of GSK's affirmative misrepresentations from its omissions because plaintiff alleges that both comprised the fraud here.

[93] *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 804 F.3d 633, 644 (3d Cir. 2015) [hereinafter *Avandia I*].

[94] *See* Pls.' Resp. Opp'n Mot. Summ. J. at 25 [Doc. No. 5544].

[95] Hileman Decl., Ex. 8, McGuire Rep., at 28, 32 [Doc. No. 5530-8].

[96] *Id.* at 28.

the same.[97] For both methods, Dr. McGuire also applies an offset "to account for an increase of Class Payor spending on other antidiabetic drugs that may have been associated with a decrease in spending on Avandia had the alleged misconduct not occurred."[98]

Additionally, Dr. McGuire, at the instruction of counsel, separately conducted what he refers to as "Metformin Calculations."[99] For those, Dr. McGuire attempted "to quantify what would have been paid by the Class Payors if they paid for metformin hydrocholoride, a first-line generic, instead of the Avandia product line."[100] Dr. McGuire concludes that, depending on the scenarios and methods applied, the estimated range of class-wide damages is between $517.9 million and $2.1 billion.[101]

Dr. McGuire is an *emeritus* Professor of Health Economics in the Department of Health Care Policy at Harvard Medical School.[102] He has an A.B. from Princeton University and a Ph.D. in Economics from Yale University.[103] He has published papers on the economics of drug prices, competition between branded and generic drug products, and insurance coverage for drugs, and has previously testified as an economic expert in cases involving the pharmaceutical industry.[104] GSK does not challenge Dr. McGuire's expertise in economics.[105]

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[97] *Id.*

[98] *Id.* at 29.

[99] *Id.* at 34.

[100] *Id.* (footnote omitted).

[101] Hileman Decl., Ex. 9, McGuire Rebuttal Rep., at 47 [Doc. No. 5530-9]. Dr. McGuire updated his damages calculations in his rebuttal report "to reflect corrections in allocating TPP class plans in the IQVIA data and to reflect updated percentages from Professor Rosenthal's analysis." *Id.*

[102] Hileman Decl., Ex. 8, McGuire Rep., at 3 [Doc. No. 5530-8].

[103] *Id.*

[104] *Id.* at 4–5.

[105] As with Dr. Rosenthal, GSK asserts a narrower argument: that Dr. McGuire is not qualified to assume the ICT-37 meta-analysis could have been completed by January 2005. GSK's Reply Supp. Mot. Exclude McGuire at 2 [Doc. No. 5557]. Because this argument is directed toward the factual underpinnings of Dr. McGuire's scenarios

1. Scenario 1: Rosenthal Adjustment

Dr. McGuire's first damages calculation under Scenario 1—the time frame from January 2005 to August 14, 2007—relies directly and entirely on the opinions of Dr. Rosenthal. Dr. McGuire calculates the difference between actual sales and but-for sales of Avandia using the 41% decrease in sales Dr. Rosenthal identified in her model.[106] He does so uncritically, as GSK pointed out during Dr. McGuire's cross-examination for the hearing on these motions:

> Q: Okay. You used [Dr. Rosenthal's] calculations in your Rosenthal adjustment then, right?
> A: Yes.
> Q: Without any adjustments to her numbers, right?
> A: I used her decrease, 41 percent. I don't think I – aside from the offset adjustment, which is something different, but I think – okay, I'll agree with that.
> Q: Okay. Therefore, if Dr. Rosenthal's numbers change, your scenarios Rosenthal adjustment damage assessment changes as well, right?
> A: So to be sure I understand, if Rosenthal would have predicted 40 percent instead of 41 percent, my estimate would change? Is that the kind of thought experiment you're asking here?
> Q: That's right. If her number is different, your damage number will be different, right?
> A: Okay.[107]

Applying the Rosenthal Adjustment, and accounting for offsets as to expected spending on other antidiabetic drugs, Dr. McGuire estimates damages of $517,882,847.[108]

Expert opinions that have been excluded under *Daubert* because they are unreliable cannot "morph into a reliable foundation" on which another expert may rely.[109] Dr. McGuire's

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and methods, the Court addresses it in conjunction with GSK's other objections regarding the reliability and fit of Dr. McGuire's methods and opinions.

[106] Hileman Decl., Ex. 8, McGuire Rep., at 28 [Doc. No. 5530-8] ("Dr. Rosenthal has provided me with the percentage decrease in sales that she estimated would occur absent the alleged misconduct. I use these percentages to calculate the amounts that would not have been paid by the Class Payors absent the alleged misconduct.").

[107] Hr'g Tr. Feb. 1, 2024, at 194–95 [Doc. No. 5568].

[108] Hileman Decl., Ex. 9, McGuire Rebuttal Rep., at 47 [Doc. No. 5530-9]. This figure also deducts rebates paid by GSK to the proposed class of TPPs, given that those rebates would not have been paid on sales that did not occur. *See* Hileman Decl., Ex. 8, McGuire Rep., at 31 [Doc. No. 5530-8].

[109] *In re TMI Litig.*, 193 F.3d 613, 705–06 (3d Cir. 1999).

Rosenthal Adjustment does just that. This "is the intellectual equivalent of having the left hand put the rabbit in the hat so it can be pulled out by the right hand."[110] Because the Court has excluded Dr. Rosenthal's opinions based on their unreliability, Dr. McGuire's opinions relying upon Dr. Rosenthal's calculations must be excluded as well.

2. Scenario 1: Step-Down Adjustment

Dr. McGuire applies the Step-Down Adjustment as an alternative calculation with respect to Scenario 1. Like Dr. Rosenthal, Dr. McGuire assumes in Scenario 1 that the impact of an earlier release of ICT-37 would be identical to the impact of the later release of the Nissen Study, and therefore the percentage decline of Avandia sales in May 2007 can simply be applied to January 2005 to arrive at a damages calculation.[111] Applying the percentage decline to that earlier point, and accounting for offsets as to expected spending on other antidiabetic drugs, Dr. McGuire estimates damages of $1,018,100,528.[112]

GSK argues that Dr. McGuire's Step-Down Adjustment is based on two assumptions not supported by the record: that ICT-37 could have been made publicly available by January 2005 and that the impact of ICT-37's publication would have been comparable or identical to the 2007 release of the Nissen Study.[113] The Court has determined that both fact questions fall within the province of the factfinder.[114] They are not grounds for exclusion under *Daubert*.

[110] *Id.* at 706.

[111] Hileman Decl., Ex. 10, McGuire Dep. Tr. July 11, 2023, at 75 [Doc. No. 5530-10].

[112] Hileman Decl., Ex. 9, McGuire Rebuttal Rep., at 47 [Doc. No. 5530-9]. This figure also deducts rebates paid by GSK to the proposed class of TPPs, given that those rebates would not have been paid on sales that did not occur. *See* Hileman Decl., Ex. 8, McGuire Rep., at 31 [Doc. No. 5530-8].

[113] GSK's Mem. Supp. Mot. Exclude McGuire at 5-6 [Doc. No. 5526-1].

[114] *Supra* Section III.A.1.

GSK also makes the broader argument that Dr. McGuire's Step-Down Adjustment is "not tied to plaintiffs' liability theory."[115] Even if it were ultimately proven that the ICT-37 results would have affected the market for Avandia in the same manner as the Nissen Study did, GSK argues that the question remains whether the Nissen Study—and, as Dr. McGuire notes in his report, the FDA's contemporaneous addition of a black-box label concerning a *greater* risk of heart failure[116]—makes sense as a proxy given the "benefits" theory of liability the Plans now pursue. GSK urges that "the relevant but-for world is one in which physicians do not receive any messaging that Avandia is cardioprotective and better than other treatments; it is not a world in which physicians receive information that Avandia is more dangerous than other treatments."[117]

The Court determined above that these assumptions, for this *Daubert* analysis, are sufficiently tailored to the Plans' benefits theory of liability.[118] Dr. McGuire's Step-Down Adjustment is sufficiently tailored to the Plans' benefits theory of liability and should not be excluded under Rule 702.

GSK makes the separate argument that the Court should exclude Dr. McGuire's damage opinions "that do not apply an offset for spending on alternative medications."[119] GSK argues that damages figures without the offset are barred as a matter of law under the Third Circuit's decision in *Avandia I* and that Dr. McGuire provides no independent justification for his methodology.[120] Rather than barring any particular damages calculation, the Third Circuit in *Avandia I* noted that damage calculations were "a question for another day," but that it should be

[115] GSK's Mem. Supp. Mot. Exclude McGuire at 4 [Doc. No. 5526-1].

[116] Hileman Decl., Ex. 8, McGuire Rep., at 8, 12 fig.2 [Doc. No. 5530-8].

[117] GSK's Mem. Supp. Mot. Exclude McGuire at 9 n.3 [Doc. No. 5526-1].

[118] *Supra* Section III.A.3.

[119] GSK's Mem. Supp. Mot. Exclude McGuire at 12 [Doc. No. 5526-1].

[120] *Id.*

simple to determine which damages are attributable to any of defendant's alleged violations.[121] Whether damages should be calculated with or without the offset is still a question for another day.[122] Dr. McGuire's opinions and testimony regarding his Step-Down Analysis for Scenario 1 may be presented both with and without offset calculations.

3. Scenario 2 (May 1999 to August 14, 2007)

With respect to Scenario 2, Dr. McGuire states in his report that he "assumes that adverse information about Avandia was available prior to any of the Avandia sales from launch and GSK conducted no fraudulent promotion."[123] Those are facially reasonable assumptions. However, Dr. McGuire goes on to state that, for Scenario 2, he was instructed by counsel to assume that "there would have been *no (or de minimis) Avandia sales*," because in that hypothetical scenario, the market would have known that "Avandia was no more safe and/or effective than lower cost alternatives."[124] In other words, and as Dr. McGuire states expressly in his report, the damages calculation he proposes for Scenario 2 amounts to "*all Avandia sales*" over eight years, from its launch in May 1999 until August 14, 2007.[125]

The assumption that, absent GSK's alleged fraudulent promotion, sales of Avandia would have been *zero* across its entire time on the market is untethered from the record. As GSK notes in its briefings, Dr. McGuire essentially "assumes that cardioprotective promotion is the only

[121] *Avandia I*, 804 F.3d at 644.

[122] *See Suchanek v. Sturm Foods, Inc.*, No. 11-535, 2017 WL 3704206, at *5 (S.D. Ill. Aug. 28, 2017) (explaining that whether a full refund is an appropriate damages model was "not a good fit for a *Daubert* motion" and refusing to exclude expert testimony on that basis); *In re Morning Song Bird Food Litigation*, 320 F.R.D. 540, 556 (S.D. Cal. Mar. 31, 2017) (approving full refund model of damages); *Montera v. Premier Nutrition Corp.*, No. 16-6980, 2022 WL 1225031, at *10 (N.D. Cal. Apr. 26, 2022) (allowing plaintiffs to proceed to trial seeking full refund damages).

[123] Hileman Decl., Ex. 8, McGuire Rep., at 32 [Doc. No. 5530-8].

[124] *Id.* (emphasis added).

[125] *Id.* (emphasis added).

reason why *any* sales of Avandia were ever made."[126] There is no factual basis for such an assumption, and Dr. McGuire cites none. Indeed, he agreed during the hearing that there are multiple factors that influence physician decision-making, and he further acknowledged that Avandia was at least "sometimes" prescribed as a second-line or third-line treatment when a patient was contraindicated for the first-line treatment, or where such treatment had failed to control a patient's diabetes.[127] Moreover, Dr. Azeez Farooki, the Plans' clinical expert, testified during his deposition that Avandia "could certainly have been prescribed . . . as a *first line drug*" for, *e.g.*, patients who could not be prescribed metformin because their "kidney function is below a certain threshold."[128] Given the complete lack of support in the record for Dr. McGuire's assumption, his opinions on damages under Scenario 2 must also be excluded.[129]

4. Metformin Calculations

Finally, Dr. McGuire explains in his report that his standalone metformin calculations represent what the proposed class of TPPs would have paid if they opted for metformin instead of Avandia.[130] The report notes that metformin generics only entered the market in 2002, so Dr. McGuire's analysis uses prices for Glucophage (the brand name for metformin) prior to 2002, and prices for both brand-name and generic metformin options after 2002.[131] Specifically, Dr. McGuire calculates "the difference in the average price per day supplied for an Avandia product and the average price per day supplied for metformin for each year," and he concludes

[126] GSK's Mem. Supp. Mot. Exclude McGuire at 9 [Doc. No. 5526-1].

[127] Hr'g Tr. Feb. 1, 2024, at 225, 227–28 [Doc. No. 5568].

[128] Hileman Decl., Ex. 23, Farooki Dep. Tr. June 1, 2023, at 26–27 [Doc. No. 5530-23].

[129] *Sterling*, 836 F. Supp. 2d at 572 (exclusion is required only where "the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury . . . ." (quoting *Child.'s Broad. Corp.*, 357 F.3d at 865)).

[130] Hileman Decl., Ex. 8, McGuire Rep., at 34 [Doc. No. 5530-8].

[131] *Id.* n.80.

that "the Class would have paid $5.79 billion less than they paid for the Avandia product line from 1999 through August 14, 2007 and $3.82 billion less from January 2005 through August 14, 2007."[132]

GSK argues that Dr. McGuire's standalone metformin calculation must be excluded because it is irrelevant.[133] A simple calculation of the difference between the price of Avandia and the price of metformin, GSK contends, assumes that there would have been no sales of Avandia at all during an eight-year period, and therefore it suffers from the same flaws as Dr. McGuire's analysis under Scenario 2.[134] The Court agrees. This case is no longer at the motion to dismiss stage, and the record has now been developed after years of discovery. While it may have been sufficient at that earlier point for the Plans to identify *some* cheaper alternative to Avandia in their pleadings, it is not sufficient at the present stage of the proceedings.

Of particular note, Dr. McGuire cites in his rebuttal report a 2011 published study finding that, six months after the FDA amended Avandia's label to add safety warnings concerning cardiovascular risk, the patients who were previously taking Avandia switched to at least six alternative treatments (or no treatment at all) in varying numbers, including not only metformin (56.6%) but also Actos (23.0%), Sulfonylurea (35.8%), Insulin (14.6%), Sitagliptin (10.8%), and Exenatide (6.2%).[135] Moreover, Dr. McGuire included several alternative treatments in addition to metformin—even if *more* expensive than Avandia—when applying the offset for alternative

[132] *Id.* at 35 (footnote omitted).

[133] GSK's Mem. Supp. Mot. Exclude McGuire at 13 [Doc. No. 5526-1].

[134] *Id.* at 13–14.

[135] Hileman Decl., Ex. 9, McGuire Rebuttal Rep., at 12 tbl.1 [Doc. No. 5530-9] (citing K.M. Hurren et al., *Antidiabetic Prescribing Trends and Predictors of Thiazolidinedione Discontinuation Following the 2007 Rosiglitazone Safety Alert*, 93 Diabetes Rsch. & Clinical Prac., no. 1, 2011, at 49).

prices under Scenarios 1 and 2, and Dr. Farooki agreed in his rebuttal report that the list of alternatives Dr. McGuire used was reasonable.[136]

In short, Dr. McGuire's metformin calculation is premised on the same kind of counterfactual assumptions as identified with respect to Scenario 2. In order to reach those calculations, Dr. McGuire must assume that *all* Avandia prescriptions were metformin prescriptions instead, and further that metformin would have been the *only* alternative that was prescribed. There is no basis in the present record for such assumptions. Accordingly, these calculations must be excluded.

## IV. CONCLUSION

For the reasons stated above, GSK's motion to exclude the opinions and testimony of Dr. Meredith Rosenthal will be granted, and GSK's motion to exclude the opinions and testimony of Dr. Thomas McGuire will be granted in part. Dr. McGuire may provide limited testimony and opinion regarding his Step-Down Adjustment for Scenario 1. An order will be entered.

[136] Third Party Payer Pls.' Affirmative Statement Facts, Ex. 20, Farooki Rebuttal Rep. ¶ 138 [Doc. No. 5546-5].